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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,512	08/26/2003	Itaru Ookubo	011350-319	2709
21839	7590	01/06/2005	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			JAWORSKI, FRANCIS J	
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			3737	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/647,512	Applicant(s) OOKUBO ET AL.	
	Examiner Jaworski Francis J.	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-13-04 (IDS).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02132004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

Specification portion page 11 lines 30 – 32 ('Here...23.') is unclear because 23 is a guidewire, and since 7 is the first or main over-the-wire/OTW lumen previously stated to alternatively house either imaging core 4 or this guidewire 23 (para [0041]) and 8 is the second or monorail/rapid exchange/RX lumen later described (para [0058]) it is unclear in this overall context whether perhaps this passage is seeking to state that the first and second lumens are of approximately the same size or for 'lumen' at end substitute -- wire -- .

The incorporation by reference of the foreign priority document to this case (para[0093]) is improper and should be cancelled.

The Examiner's reasoning is that applicants have established a proper foreign priority claim under 35 U.S.C. 119 by stating such claim in the oath and providing a certified copy of their foreign application. (see MPEP Section 201.14). Since the priority document is in a foreign language, in the event of an intervening reference at any time during prosecution its use is not disallowed by the mere presence in the spec of para [0093] since a certified translation of the priority document would be required. (See MPEP Section 201.15). In the event of a new matter issue, a mere global reference to another document is not an incorporation of anything for purposes of 112, meaning that

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a specific portion of the priority document would need to be identified and translated. (see MPEP Section 608.01(p) I. A in general). Since the incorporation be it characterized as essential/non-essential is improper in format as it relies upon a foreign application (see MPEP Section 608.01(p) I.A2) and since it serves no apparent advantage regarding prior art or disclosure adequacy issues over its absence its cancellation is requested.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1 –2 and 4 – 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to base claim 1 the language found in lines 22 – 26 appears to be an attempt to claim the feature set forth on page 14 lines 20 – 23 of the specification, namely that there is a range of overlap between the first and second lumen passageways which may be in the range of 0 – 60 mm whether the first embodiment of Fig. 3 (where the first lumen end-opening exits internally of the catheter-sheath as per later claim 4) or the second embodiment Fig. 5 (where said end-opening exits externally as per later claim 5) is being claimed . However the literal language ‘in relation to a position at a distance of 60 mm’ is vague in that a relation may be any relation including

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one which exceeds such distance and the relationship is one of deficit. Additionally applicants are defining this distance as beginning or from the first distal end of the first lumen hence the appropriate language would appear to be --towards-- for 'to' in line 25 and --along--for 'in' in line 26.

Only claim 3 escapes this deficiency insofar as it contains a clear claiming of a spacing range..

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Jang (US5976093).

Under a first interpretation Jang teaches in Fig. 4 or Fig. 7a catheter or sheath having a first lumen or passageway with proximal and distal end portions and passage (either of lumen 64 or 66 or 106 or 122) having a first axis and a first distal end portion and a second sheath lumen or passageway with such proximal and distal portions and passage (other of 64, 66) such that the so-defined first lumen empties into the second lumen (Claim 4 feature) where the second lumen proceeds to exit externally and more distally and therefore the first and second lumens have a coextensive overlap (relationships unspecified per ambiguity discussed supra). Under an alternative of this

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first interpretation with the spacing relationship a negative one, the first lumen continues as the catheter very tip and therefore opens to the exterior of the second lumen passage (Claim 5 feature), with passages overlapping to an unspecified extent and no weight given to '60 mm' in the ambiguous context.

Under a second interpretation the base claim is interpreted as more narrowly defining the 0-60 mm overlap in spite of the ambiguous wording in order to expedite prosecution. Then in consideration of the Jang col. 6 lines 3 – 7 instruction to provide a distal neckdown of from 1 – 20cm length i.e. 10 – 200 mm length, the overlap depicted in the Fig. 7 drawing reasonably falls in the 10 mm range with the interpretation otherwise as above.

Otherwise an ultrasound imaging core is directly taught.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jang as applied against claim 6, further in view of Pomeranz (US5095911). Whereas the former does not specifically teach covering the imaging core with a protective tubing, it would have been obvious in view of the latter elements 16, 22 to do so since the art had discovered that imaging and guidewire functions could be combined into an imaging

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guidewire structure however the relative frailty of the device under mechanical rotation necessitates that the imaging core be protected by a housing tubing.

Claims 1 – 6 are further rejected under 35 U.S.C. 103(a) as being unpatentable over Jang as applied to claims 1-6 above, and further in view of Moore et al (US5531700).. The former is applied as above. Since in a later improvement patent Moore and Jang realized that in a low profile catheter sheath (single passageway at most distal tip) the forming of local exit lumens within 5cm of the tip (24) and/or close to the passageway junctures (e.g. 30) facilitated rapid exchange, it would have been obvious to so modify Jang as earlier applied regarding specific attention to spacings, in order to facilitate rapid catheter exchange.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jang in view of Moore et al as applied to claim 6 above, and further in view of Pomeranz as the latter was applied against this claim above.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jang as applied to claim 1 above, and further in view of Yock (US5501227). Under the narrow interpretation that claim 5 pertains to applicants second embodiment having parallel passageway axes and external exiting lumens for the device as in applicants' Fig. 5 where the RX passageway 8 contains a short overlap with and then exits distal to the main imaging lumen exit of 7, and that Jang Fig. 7 shows dual lumens but not external exit of the RX lumen or protrusion or full parallelism thereof, it would have been obvious in view of Yock Fig. 12 to extend second or guidewire lumen 81 slightly beyond the catheter while maintaining parallelism all along the overlap with dual

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external exits of the passageways because Yock like Jang is also directed to the use of an ultrasound imaging core as well as rapid exchange, see col. 8 lines 44 – 56 preceding the Fig. 12 discussion therein.


The following additional art is cited as of interest:

Narrow exit profile guidewire catheter reinforcements – Ginn et al (US5443457) elements 26, 62, 88, 128, 130; Willard et al (US602231) element 60.

Short RX guidewire para-axial segments – Leary et al (US5024234) 138, 140, 144; Jayaraman (US6312406) Figs. 3 – 12.

Neckdown profile i.e. single distal end-lumen catheters – Griffith (US5400789) col. 6 lines 3 – 26; Fugoso et al (US5545138); Ginn (US5540236).

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.


Francis J. Jaworski
Primary Examiner

FJJ:fjj

01-03-2005